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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,604	08/18/1999	RAGUPATHY MADIYALAKAN	AREX-P03-004	6693
7590 Matthew P Vincent Ropes & Gray One International Place Boston, MA 02110		06/04/2007	EXAMINER CANELLA, KAREN A	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 06/04/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/376,604	<b>Applicant(s)</b> MADIYALAKAN ET AL	
	<b>Examiner</b> Karen A. Canella	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 276-351 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 276-282, 288-295, 297, 299-302, 308, 313-315, 317, 319, 328, 333-335, 337, 339-351 is/are rejected.
- 7) ☐ Claim(s) 283-287, 296, 298, 303-307, 309-312, 316, 318, 320-327, 329-332, 336 and 338 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>May 25, 2006</u> | 6) <input type="checkbox"/> Other: ____  |

### DETAILED ACTION

Claims 276-278, 287, 307 and 327 have been amended. Claims 339-351 have been added. Claims 276-351 are pending and under consideration.

Claims 276-282, 299-302, 313-315, 319, 334, 335, 339-351 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30, 71, 76, 85-88, 96, 99, 100, 103-114, 117-119, 123-134 of copending Application No. 09/152,698 in view of Schwartz et al ('Cancer Markers', In: Cancer: Principles and Practice of Oncology, DeVita et al, Ed.s, 4<sup>th</sup> Edition, 1993, pp. 531-542, reference of the IDS filed May 26, 2006).

Claims 276-282, 299-302, 313-315, 319, 334 and 335 of the '698 application anticipate the instant claims to the extent that an immune complex of CA125 is administered rather than the administration of the anti-CA125 antibody.

Schwartz et al teach that the CA125 is a sero-marker for ovarian cancer (Table 21-5).

It would have been prima facie obvious at the time the claimed invention was made to administer the CA125 antibody rather than the immune complex to patients having high levels of circulating CA125 antigen. One of skill in the art would have been motivated to do so by the teachings of Schwartz et al on the presence of the CA125 antigen in patient serum. One of skill in the art would understand that the immune complex would form in vivo with free circulating tumor antigen.

This is a provisional obviousness-type double patenting rejection.

Claims 276-278, 288-295, 297, 308, 313-315, 317, 328, 333-335, 337, 339-342, 346, 347-351 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-29 of U.S. Patent No. 6,716,966. Although the conflicting claims are not identical, they are not patentably distinct from each other because the requirement for eliciting the effective host T-cell response and a host immune response against a second epitope of the CA15.3 antigen would be inherent in the methods of the '966 patent which provide for the administration of the Alt-1 antibody which binds to MUC1 (CA-15-3).

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Claims 283-287, 296, 298, 303-307, 309-312, 316, 318, 320-327, 329-332, 336 and 338 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicants arguments.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

5/13/2007

  
KAREN A. CANELLA Ph.D.  
PRIMARY EXAMINER